Attorney Docket No.: P29911 U.S. Application No. 10/579,449

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Mariko KURODA et al.	Confirmation No.: 8465
Appln. No.	: 10/579,449	Group Art Unit: 1797
I.A. Filed	: November 17, 2004	Examiner: Denise R. ANDERSON
For	: HOLLOW FIBER MEMBRANE FOR BLOOD PURIFICATION AND BLOOD PURIFICATION APPARATUS USING THE SAME	

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendments
Randolph Building
401 Dulany Street
Alexandria VA 22314

Sir:

I, Mariko Kuroda, of 5731-1, Igata-cho, Nobeoka-shi, Miyazaki, 889503, Japan, declare as follows:

1. That I am a named inventor of the invention disclosed in U.S. Patent Application No. 10/579,449, filed as PCT/JP2004/017082 on November 17, 2004 (hereinafter referred to as "the patent application"), and claiming priority to Japanese Patent Application Nos. 2003-386582, filed November 17, 2003 and 2004-030160, filed February 6, 2004.

2. That I hold the degree of Bachelor of Science awarded from the School of Agriculture at Kyushu University in March of 1992.

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3. That I have been employed with Asahi Kasei Kuraray Medical Co., Ltd, Development Planning Department at Nobeoka, Dialysis Products Division (formerly Asahi Kasei Co. Ltd., HF Development Planning Department) since April of 1992.

4. That I have published the following articles under my maiden name Mariko Nakayama:

- "Studies on proteins attached to dialysis membrane," Kidney and Dialysis, vol. 38, Supplementary Volume "High performance membrane '95", pp. 70-73;
- "Artificial Dialysis," Senni Kikai Gakkaishi (Journal of Textile Engineering), vol. 50, no. 4, pp. 213-215; and
- "Vitro evaluation of Vitamin E immobilized PS membrane," Kidney and Dialysis, vol. 59, Supplementary Volume "High performance membrane '05", pp. 120-122.

5. That I have reviewed the Office Action dated January 14, 2008 in the patent application, in which claims 1-4, 6, and 7 are rejected under 35 U.S.C. §102, as allegedly anticipated by WO 2002/087735, July 11, 2002 as evidenced by its U.S. counterpart, U.S. Patent Application Publication No. 2004/0167237 A1 to Kim et al. Furthermore, in the Office Action, Kim et al. is relied upon as primary document in an obviousness rejection of claims 5, 8, and 9.

6. That I understand that an accurate comparison of the fiber of Kim et al. to the presently claimed invention is necessary for determining whether or not Kim et al. anticipates the present claims.

7. That the following experiments are performed so that an accurate comparison can be made.

8. That a hollow fiber membrane according to Kim et al. was prepared by the following process:

(1) Preparation of a Spinning Solution

A homogenous spinning solution consisting of 18 parts by weight of an aromatic polysulfone (UDEL P-1700 manufactured by Amoco Engineering Polymers, Inc.), 7 parts by weight of polyvinyl pyrrolidone (manufactured by ISP Inc., K-30; weight-average molecular weight 40,000), and 76 parts by weight of N-methyl-2-pyrrolidone (manufactured by Kanto Chemical Co., Inc.) was prepared. The homogenous spinning solution was prepared by stirring and dissolving the mixture of all these compounds at 50 °C.

(2) Prepraration of a hollow fiber membrane

The spinning solution was maintained at 50 °C and extruded from a double cylindrical spinneret (the size of the cylindrical spinneret is 0.1 mm – 0.2 mm – 0.3 mm) simultaneously with an inner cylinder fluid consisting of 50 parts by weight of water and 50 parts by weight of N-methyl-2-pyrrolidone. The extruded hollow fiber was run through a hood saturated with water vapor at an average temperature of 40 °C, immersed into a water bath at 55 °C installed 600 mm below the spinneret, and wound around a bobbin at a rate of 50m/min. No intentional stretching was conducted during this process.

(3) Post treatment

The wound hollow fiber was washed with hot water at 90 °C for 90 minutes, dipped in a 20 wt% glycerol aqueous solution at 60 °C for one hour and dried at 70 °C to obtain a hollow fiber for further evaluation.

9. That the hollow fiber membrane obtained by the method described under paragraph 8 was measured by the following method:

(1) A sample was prepared from a bundle of the hollow fiber membrane by cutting 1400 ± 5 mm of the hollow fiber membrane into piece having length of 50 ± 5 mm. The outside surface of the bundle was embedded with a resin along the longitudinal direction while keeping the cut ends open.

(2) The sample was set to a zeta potential analyzer (EKA manufactured by Anton Paar) and a solution prepared by mixing 0.001 mol/l aqueous potassium chloride solution with 0.01 mol/l aqueous potassium hydroxide to give a pH of 10 to 11 was charged into the opening of the bundle of hollow fiber membranes of the sample to measure the zeta potential. Zeta potentials were measured in dependence of the pH by titrating the sample with a 0.1 mol/l aqueous hydrochloric acid solution in a pH range from 10.8 to 3.4

10. That in further description to the method described under paragraph 9, the electrolyte passes only the inner surface of the hollow fiber membrane. The large number of hollow fibers used during the measurement and the controlled conditioning of the ionic charges on the inner

surface with change of the pH result in excellent reproducibility and predictability of membrane properties when used for blood purification.

11. That the measured data are depicted in Figure 1 of Appendix A. The zeta potential at pH 7.5 was determined by plotting the measured data and extrapolating the titration curve over the measured pH range with a polynomial trendline having a third order. As evidenced in Figure 1 of Appendix A, the zeta potential of the hollow fiber at pH 7.5 was + 4.0 mV (see intercept of curve with y-axis).

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code, and that such willful false statements may jeopardize the validity of the patent application or any patent issuing thereon.

Mariko Kuroda
Mariko Kuroda

2008. 6. 16
Date

Enclosure: Appendix A (1 page)

Appendix A

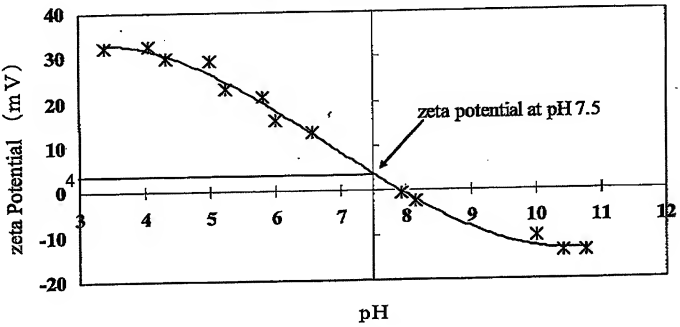

Figure 1: The zeta potential of the hollow fiber membrane measured over a pH range of 10.75 and 3.4. The plotted data were extrapolated with a polynomial trendline of a third order. At pH 7.5, the zeta potential was determined to be +4.0 mV.